K022769

BIONOSTICS

NOV 13 2002

510(k) Summary[1]

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Contact Person

Kathleen Storro
Director, QA & Regulatory Affairs
(978) 772-7070 x 220

Date of preparation of this summary: 15 August 2002

(2) Device trade or proprietary name: LifeScan OneTouch Ultra control solution

Device common or usual name or classification name:

Single Analyte Control, All Types (Assayed and Unassayed)

PRODUCT NOMENCLATURE	CLASSIFICATION NUMBER	CLASS	PANEL
SINGLE ANALYTE CONTROL SOLUTION	862.1660 75 JJX	I	CHEMISTRY

(3) Substantial Equivalence

There has been no change in formulation, labeling or intended use of the control solution since the original 510(k) submission, K000318. The purpose of this 510(k) submission is to extend the use of this control to all LifeScan family of meters using the OneTouch Ultra or OneTouch FastTake glucose test strips, namely:

OneTouch FastTake Blood Glucose Meter, K011479
InDuo Blood Glucose Meter, K011616
UltraSmart Blood Glucose Meter, K021819

(4) Description of the new device

LifeScan OneTouch Ultra control solution is a single-level, viscosity-adjusted, aqueous liquid glucose control solution. **LifeScan OneTouch Ultra control solution** provides a convenient method of performing periodic QC checks for laboratories selecting to measure liquid QC material as a part of their quality assurance program. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.

LifeScan OneTouch Ultra control solution contains glucose representing typical, normal-range glucose values in blood to verify performance of LifeScan BGM systems using the OneTouch Ultra or OneTouch FastTake test strips.

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[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

LifeScan OneTouch Ultra control solution is a non-hazardous aqueous solution containing no biological materials.

(5) Intended use of the device

LifeScan OneTouch Ultra control solution is intended to be used to monitor and evaluate the analytical performance of LifeScan BGM family systems using the OneTouch Ultra or OneTouch FastTake test strips.

(6) Technological characteristics of the device.

This material consists of viscosity-adjusted, aqueous glucose control solution prepared in to represent normal, whole blood glucose values. The solution has been optimized to simulate the response of whole blood on LifeScan BGM family systems using the OneTouch Ultra or OneTouch FastTake test strips.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability
b) Stability after opening
c) Test precision and range

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2002

Ms. Kathleen Storro
Director, QA and Regulatory Affairs
Bionostics, Inc.
7 Jackson Road
Devens, MA 01432

Re: k022769
Trade/Device Name: LifeScan OneTouch Ultra Control Solution
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: August 19, 2002
Received: August 21, 2002

Dear Ms. Storro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K022769

Device Name: LifeScan OneTouch Ultra control solution

Indications for Use:

LifeScan OneTouch Ultra control solution is intended for use to verify the performance of LifeScan BGM systems using the OneTouch Ultra or OneTouch FastTake test strips at glucose levels within the reportable range. The Glucose Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022769

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)